Case 1:05-cv-00586-GMS

Document 37-2 Filed 01/06/2006 Page 1 of 55

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Charles R. Krikorian charles krikorian@kattenlaw.com 312.902.5667 direct 312.577.4645 fax

July 19, 2005

By Facsimile (954/382-7745) and Federal Express

Ted Whitlock, Esq. Intellectual Property Counsel Andrx Corporation 8151 Peters Road - 4th Floor Plantation, Florida 33324

Dear Mr. Whitlock:

Our firm acts as outside counsel to Biovail Laboratories International SRL and its related companies ("Biovail"). We are in receipt of a copy of your letter dated June 22, 2005 concerning Andrx's ANDA for Cardizem LA®. The information provided in that letter is insufficient to permit Biovail to determine whether Andrx's proposed product likely to be made pursuant to ANDA No. 77-686 infringes one or more claims of United States Patent Nos. 5,288,505 and 5,529,791, or to conclude that Biovail is estopped under either issue or claim preclusion from asserting those patents against Andrx in respect to ANDA No. 77-686. See, e.g., Bayer AG v. Biovail Corp., 279 F.3d 1340 (Fed. Cir. 2002).

In order to continue our analysis of the issues, Biovail requires the following additional information:

- 1. the remainder of Andrx's ANDA No. 77-686;
- 2. any information relating to any testing by or on behalf of Andrx comparing its proposed drug product likely to be made pursuant to ANDA No. 77-686 and any product made pursuant to Andrx's ANDA No. 75-401;
- 3. any electron micrographs of any drug product made pursuant to ANDA No. 77-686;
- 4. the results of any *in vivo* testing of any drug product made pursuant to ANDA No. 77-686;
- 5. any information relating to any comparison of a drug product made pursuant to ANDA No. 77-686 and any other dilitiazem drug product; and
 - 6. samples of any drug product made pursuant to ANDA No. 77-686.

Please inform me as to when we can expect to receive these items.

Katten Muchin Rosenman LLP

Ted Whitlock, Esq. July 19, 2005 Page 2

Please also be advised that Biovail's requests should in no way be viewed as Biovail's agreement that the terms of the Offer of Confidential Access have any applicability to any litigation concerning ANDA No. 77-686, either as part of any Protective Order or otherwise.

Sincerely,

Charles R. Krikorian

CRK:cc

cc: Eric C. Cohen, Esq.

Kenneth C. Cancellara, Q.C.

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August 4, 2005

By Facsimile

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Ted Whitlock, Esq.
Intellectual Property Counsel
Andrx Corporation
8151 Peters Road - 4th Floor
Plantation, Florida 33324

Re: Andrx's Cardizem LA 420 mg ANDA

Dear Ted:

This confirms your voice mail message of late yesterday indicating that Andrx is preparing to send to our Firm as soon as possible the information requested in Charles Krikorian's July 19, 2005 letter.

You also asked in your message that we let you know the amount of samples Biovail seeks. Please provide 2 grams each of the individual ingredients, e.g., sugar spheres, identified in the "Components" section of Exhibit A attached to Andrx's June 22, 2005 notice letter to Biovail (copy attached). In addition, please provide 2 grams each of Andrx's active pellets and extended-release pellets, as identified in the "Composition Statements" section of Exhibit A, and 120 tablets of Andrx's proposed generic Cardizem LA 420 mg product.

For the samples of active pellets, extended-release pellets and tablets, please identify the lot or batch number from which they were manufactured, and provided copies of the manufacturing batch records corresponding to those samples. For the samples of the components, please supply them from the same raw material lots as were used in the active pellets, extended-release pellets, and tablets that Andrx is supplying to us. We request that these samples be shipped to me in the same manner that they were shipped to Andrx and in a manner that is consistent with the handling requirements in Andrx's Cardizem LA 420 mg ANDA.

Ted Whitlock, Esq. August 4, 2005 Page 2

Finally, as we discussed today, in preparing its Notice Letter, you indicated that Andrx omitted the last page of the "Request for Confidential Access to Information," (Exhibit D of Andrx's notice letter), which included a signature line. You asked that we sign a complete version of that agreement, which would allow persons from our Firm to have access to Andrx's confidential information. Enclosed is an executed version of that agreement.

If you have any questions, please call me.

Very truly yours,

Dominick A. Conde

Attachments

DAC:ceo

NY_MAIN.516842v1

-Section VII.

COMPONENTS AND COMPOSITION STATEMENTS

All components used in the manufacture of Diltiazem Hydrochloride Extended Release Tablets are identified in this section. Detailed information on each component, the manufacturers and the drug master files (DMF) they currently maintain, are provided in Sections VIII(1) and VIII(2) of this

COMPONENTS

Diltiazem Hydrochloride Extended Release Tablets, 420 mg

Ingredient Hydrochloride Extended	i i	
Diltiazem Hydrochloride	Grad	e Function
Candelilla Wax Powder, FCC	USP	Active
Colloidal Silicon Dioxide (Cab-O-Sil M-5P))	N/A	Polishing Agent
Ethylcellulose, (Ethocel 10cps)	NF	Glidant
	NF	Binder (non-release controlling
Hypromellose 2910	USP	
Isopropyl Alcohol*	USP	Coating (release controlling) Solvent
Magnesium Stearate		Solvent
	NF	Lubricant
Microcrystalline Cellulose (Avicel PH 101)	NF	Diluent
Nitrogen**		
Opadry II White Y-30-18037	NF	Purging and blanketing agent
Containing: Lactose Monohydrate, NF Hypromellose 2910 (ISP)	N/A	Color Film Former
Titanium Dioxide, USP Triacetin USP	·	
Polyacrylate Dispersion 30 Percent, EP (Eudragit NE 30D) which contains 1.5% Nonoxynol 100	EP.	Coating (release controlling)
Polyethylene Oxide, 10-20 mesh Polyox WSR N-80)	NF	Gel forming agent (release controlling)
olysorbate 80	NF	Surfactant (non-release
ovidone K-30		controlling) Binder (non-release controlling)
urified Water*		Solvent
ngar Spheres, (30/35) (contains Corn starch)		
	NF I	Filler (non-release controlling)
lc, (Altale 500V)	USP [abricant (non-release

^{*}Evaporated during processing.

^{**} Used for purging and blanketing.

COMPOSITION STATEMENTS 2.

Ingredient	% w/v	release Tablets, 420 mg Table (mg/tab)
Advertises to the second secon		To an in the same of the same
Diltiazem Hydrochloride, USP		
Ethylcellulose, USP (Ethocel 10cps)	34.31	420.0
Povidone K-30, USP	2.09	25.54
Sugar Spheres, NF(30/35)	1.04	12.71
Isopropyl Alcohol, USP*	8.32	101.8
<u> </u>		*
Nitrogen, NF++	**	
distributed and the state of th		**
Hypromellese 2010, 11ch o		
Hypromellose 2910, USP (Methocel ES Premium) Isopropyl Alcohol, USP	0.05	0.6366
Magnesium Stearate, NF	•	•
	0.66	8.057
Polyacrylate Dispersion 30 Percent, EP (Endragit NE 30D)		
Which contains 1.3% Nonoxynol 1001	3.85	47.16 (solid) 157.2
Polysorbate 80 NF	0.01	
Purified Water, USP		0.1061
Talc, USP (Altale 500V)	0.66	-
phoreto and a market	0.00	8.057
Wighten CT		
olloidal Silicon Dioxide, NF (Cab-o-Sil)		1
Company Change NE	0.25	3.000
Aagnesium Stearate, NF	0.98	
	0.98	12.00
ficrocrystalline Cellulose, NF (Avicel PH 101)	21.56	263.9
olyethylene Oxide, NF 10-20 mesh (Polyox WSR N-80)	24.26	297.0
lovernor de la companya de la compa		British British State Control
ndelilla Wax Powder, FCC		
	0.049	0.6000
adry II White Y-30-180372	1	
	1.912	16.40 - 30.40
nfied Water, USP		
TOTAL	100.00	1224
and dist		

^{*}Evaporated during process

¹ Eudragit NE 30D is a 30% aqueous dispersion of a neutral copolymer based on ethyl acrylate and methyl methacrylate. It contains approximately 1.5% nonoxynol 100. Thus the finished product contains approximately 0.7074 mg of nonoxynol 100.

*Ingredients in Opadry II White Y-30-18037	%w/w in Opadry II White Y-30-18037	Amount per tablet (mg)	%w/w per tablet
Hypromellose 2910, USP	28.00	4:502 0.510	
Lactose Monohydrate, NF	40.00	4.592 - 8.512	0.5353
Titanium Dioxide, USP	24.00	6.560 - 12.16	0.7647
Triacetin USP	8:00	3.936 - 7. <u>2</u> 96	0.4588
Total	100.00	1.312 - 2.432	0.1529
	100.00	16.40 - 30.40	1.912

^{**} Used for purging and blanketing.

^{***}Range based on the average of 100 tablets

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August 26, 2005

By Mail and Facsimile

WASHINGTON OFFICE

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(202) 530-1010 FACSIMILE (202) 530-1055

> Herschel Sparks, Esq. Andrx Corporation 8151 Peters Road - 4th Floor Plantation, Florida 33324

> > Re: Andrx's Cardizem LA 420 mg ANDA

Dear Herschel:

This is further to my voicemail of August 23, 2005 to you seeking the status of samples relating to Andrx's proposed generic 420 mg Cardizem LA product that were requested in my August 4, 2005 letter to Ted Whitlock.

In your August 24 voicemail to me, you stated that Andrx had fallen behind on collecting the requested samples, but now the process has been started. However, you were not sure when that process would be completed. Please provide us an estimate as to when the requested samples will be ready for shipping, so that we can make preparations to complete our analysis of the Andrx materials promptly.

Additionally, your voicemail indicated that Andrx would like to have the complaint served prior to sending us samples. We do not understand why Andrx now apparently needs to have the complaint served prior to providing samples.

truly yours,

Please feel free to call me to discuss.

DAC:ceo

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September 2, 2005

By Mail and Facsimile

Herschel Sparks, Esq. Andrx Corporation 8151 Peters Road - 4th Floor Plantation, Florida 33324

Re: Andrx's Cardizem LA 420 mg ANDA

Dear Herschel:

This is in response to your August 30, 2005 email regarding service of Biovail's complaint against Andrx.

Andrx's explanation why it will not provide samples prior to being served Biovail's complaint makes little sense particularly since Andrx agreed to provide samples before Biovail filed its complaint. As previously explained to Ted Whitlock, Biovail is not on a fishing expedition, and there is no dispute that the requested samples are relevant to Biovail's complaint. Moreover, Andrx's reliance on Local Rule 4.1 is also clearly misplaced since under Rule 4(m) of the Federal Rules, Biovail has 120 days to serve the complaint.

Nevertheless, in the spirit of cooperation, Biovail will serve its complaint in the next few days.

Also, please let us know when we can expect to receive the samples requested in our August 4, 2005 letter.

Very truly yours,

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September 20, 2005

VIA FACSIMILE

FACSIMILE (202) 530-1055

Herschel Sparks, Esq. Chief Litigation Counsel Andrx Corporation 8151 Peters Road, 4th Floor Plantation, Florida 33324

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586

Dear Herschel:

This letter is further to my September 2, 2005 letter regarding samples from Andrx that were requested by Biovail on August 4, 2005.

Andrx previously stated it would not provide samples until it had been served with the summons and complaint. Biovail's summons and complaint, however, was served nearly two weeks ago, on September 7th, yet to date we have not received any samples. Accordingly, please let us know when we can expect to receive the samples requested in my August 4, 2005 letter.

[] /

Dominick A Conde

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September 27, 2005

VIA FACSIMILE

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SHINGTON, D.C. 20006-1110

William J. Cattie, III, Esq. Rawle & Henderson, LLP 300 Delaware Avenue, Suite 1015 P.O. Box 588 Wilmington, DE 19899-0588

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586

Dear William:

We represent Biovail in this matter. To date, Biovail has asked Andrx on five separate occasions for samples in conjunction with its Cardizem LA 420 mg Paragraph IV filing. Attached for your review are the five letters relating to this request dated July 19, 2005, August 4, 2005, August 26, 2005, September 2, 2005 and most recently September 20, 2005.

Despite making these requests two months ago and despite Andrx's continuous representation that it would provide the requested samples, we have not yet received any samples. Accordingly, please let us know when we can expect to receive the samples as requested.

Very trylly yours

Jominick A &

William J. Cattie, III, Esq. September 27, 2005 Page 2

Attachments

cc: Martin P. Endres, Esq.
Steven Maddox, Esq.
Jack B. Blumenfeld, Esq.

HEDMAN & COSTIGAN, P.C.

ATTORNEYS AT LAW

JAMES V. COSTIGAN
KENNETH F. FLOREK
ALAN B. CLEMENT
MARTIN P. ENDRES
KATHLEEN A. COSTIGAN
JOHN F. VOLPE
KATHARINE G. LOVING
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EDWARD A. HEDMAN 1927-2004

> TELEPHONE (212) 302-8989

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October 4, 2005

mail@hgcpatent.com

OF COUNSEL CHARLES A. MUSERLIAN

Joseph M. O'Malley, Jr., Esq. FITZPATRICK, CELLA, HARPER, & SCINTO 30 Rockefeller Plaza New York, NY 10112

Re:

Cardizem® LA Litigation

Biovail Labs. Int'l SRL v. AndrxPharms., LLC, et al.

Case No. 05-586 (D. Del.) Our Ref. No.: 141-v-504

Dear Mr. O'Malley:

Enclosed is production which Andrx Pharmaceuticals, LLC ("ANDRX") is producing in the above-referenced matter. This production consists of ANDRX 00001-00022 (samples of Andrx product) and is designated highly confidential pursuant to the terms of the protective order entered in this matter.

Very truly yours,

HEDMAN & COSTIGAN, P.C.

Matthew J. Solow

MPE/MJS

cc: William J. Cattie, III, Esq. (via facsimile) Steven Maddox, Esq. (via facsimile)

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October 7, 2005

VIA FACSIMILE

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Matthew J. Solow, Esq. Hedman & Costigan, P.C. 1185 Avenue of the Americas New York, NY 10036

Re:

Biovail v. Andrx Pharmaceuticals LLC et al...

Civil Action No. 1:05-cv-586

Dear Mr. Solow:

This concerns the samples Andrx sent Biovail on October 4, 2005 as well as Biovail's requests for information regarding Andrx's proposed generic Cardizem LA 420 mg product.

First, Andrx did not send samples of its active pellets as specifically requested in Biovail's August 4, 2005 letter. Please promptly provide the requested samples.

Second, Andrx sample designated ANDRX 00012 does not indicate the quantity of the sample. Please provide a new sample with the quantity as well as the description, raw material code, raw material number, and sampling date clearly identified.

Third, Andrx samples designated ANDRX 00020 and ANDRX 00021 were received damaged. Biovail has not opened any of the Andrx samples. ANDRX 00020 and ANDRX 00021, however, were received with a visibly wet substance on the exterior of the sample bottles. In addition, the ink on the labels of these samples is running, making them illegible. Please provide new samples of these materials, and confirm that the damaged samples will not have any effect on the other Andrx samples.

Fourth, please let Biovail know how Andrx shipped the samples to you.

Matthew J. Solow, Esq. October 7, 2005 Page 2

Finally, Andrx has not provided the requested information set forth in numbered categories two through five of Biovail's July 19, 2005 letter (copy attached at Tab A). Without this information and all of the requested samples, Biovail will not be able to complete its analysis.

Very truly yours,

Preston K. Ratliff II

Attachment

cc: William J. Cattie, III, Esq. Martin P. Endres, Esq. Steven Maddox, Esq. Jack B. Blumenfeld, Esq.

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November 29, 2005

VIA FACSIMILE

Steven A. Maddox, Esq. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007-5143

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Maddox:

This is in response to Andrx's November 23, 2005 letter regarding Biovail's November 4, 2005 discovery proposal and November 21, 2005 initial disclosure statement.

First, as requested, Biovail will copy Martin Endres and Herschel Sparks on its letters. In this regard, Biovail notes that Andrx has not copied Biovail's local counsel Jack Blumenfeld on its letters. Please copy Mr. Blumenfeld on all future correspondence.

Second, regarding discovery from the prior litigation, Civil Action No. 98-Civ-7096 (S.D. Fla.), Biovail will identify the documents that it produced by Bates number provided that Andrx agrees to do the same for the documents that it produced. As for Andrx's request for a "complete list of all depositions of Biovail and third parties taken in the prior litigation," Andrx was the sole defendant in that litigation, and accordingly there is no one better than Andrx itself to identify what depositions it took of Biovail and of third parties. To the extent that Biovail took third party depositions, it will identify them provided that Andrx agrees to do the same for the third party depositions it took.

Third, Biovail understands that Andrx has accepted its proposal to provide samples and responsive documents by December 30, 2005. Please, however, confirm as requested previously in Biovail's November 10, 2005 letter that Andrx's production by that date will include its samples and documents for all proposed strengths of generic Cardizem LA, including those strengths that are the subjects of Civil Action No. 05-730. Please also

Steven A. Maddox, Esq. November 29, 2005 Page 2

let Biovail know whether Andrx will agree to a stipulation consolidating the two cases. Note that at this point, Biovail does not necessarily agree that the two cases can be consolidated under the existing schedule. Certainly, if Andrx does not agree to provide discovery on all of its proposed strengths, including samples, by December 30, 2005, Biovail does not believe it will be possible to consolidate the cases without an appropriate extension of the schedule.

Fourth, Biovail disagrees with Andrx's characterization of its initial disclosures as "manifestly inadequate as to amount to a willful violation of the Federal Rules." Biovail's initial disclosures are in full compliance with Federal Civil Procedure Rule 26 as they identify the persons and documents, as presently advised, that Biovail may use to support its claims and defenses. Biovail's claim is for infringement. None of the persons listed in Andrx's letter will have any discoverable information regarding whether Andrx's formulation meets the claims of the '791 patent. That claim, as Andrx knows, will be decided based on information in Andrx's possession, including Andrx documents and samples. If Andrx has contrary authority, please let Biovail know and Biovail will consider it. Biovail also notes that many of the persons Andrx seeks identification of relate not to any claim of Biovail, or any articulated defense of Andrx, but relate only to secondary considerations of nonobviousness. Andrx's notice letter asserted only non-infringement and res judicata, and because no obviousness defense has been raised in this case (boilerplate aside), there would have been absolutely no reason to identify any such persons in Biovail's initial disclosures. If Andrx fully articulates and supports a prima facie obviousness position in response to Biovail's interrogatories to be served this week, Biovail will, to the extent it chooses to rely on them, identify its proofs of secondary considerations in response to an appropriate Andrx interrogatory requesting such information.

Fifth, Biovail will return the samples that Andrx provided on October 4, 2005 if Andrx agrees that it will provide Biovail new samples for all of its proposed strengths by December 30, 2005.

Finally, Biovail expects to provide Andrx a draft protective order by the end of the week.

Very truly yours,

Preston K. Ratliff II

cc: Jack B. Blumenfeld, Esq. William J. Cattie, III, Esq. Martin P. Endres, Esq. Herschel Sparks, Esq.



FOLEY & LARDNER LLP ATTORNEYS AT LAW

WASHINGTON HARBOUR 3000 K STREET, N.W., SUITE 500 WASHINGTON, D.C. 20007-5143 202.672.5300 TEL 202.572.5399 FAX www.foley.com

December 6, 2005

WRITER'S DIRECT LINE 202.672.5465 smaddox@foley.com EMAIL

CLIENT/MATTER NUMBER 054657-0103

Preston K. Ratliff II, Esq Fitzpatrick, Cella, Harper & Scinto 30 Rockefeller Plaza New York, NY 10112-3801

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586

Dear Mr. Ratliff:

I write in response to your letter of November 29, 2005.

Andrx calls upon Biovail to stipulate to consolidation of the two cases, both of which assert the same patent and are based on the same Andrx ANDA as amended. As you will see in our forthcoming response to Biovail's document requests, the documents and samples that Andrx agrees to produce will include all dosage strengths covered by the ANDA as amended.

If Biovail does not agree that the resultant consolidated case should proceed under the current scheduling order, please advise us immediately of that position and any purported justification, so that we may seek the Court's intervention without delay.

Regarding your Rule 26 statement, there is nothing else to say. We have your position. You have ours. We view any meet and confer obligation as having been discharged. We will prepare our motion to compel and for sanctions.

I do not believe that we received the draft protective order that you indicated you would send by December 2, 2005. In order to alleviate our concerns about delay, please confirm that Biovail will produce all documents on December 30, 2005, even if a protective order has not yet been entered – subject to an attorney's eyes only agreement. If you will not so agree, please explain exactly why it has taken more than a month for you to provide the draft that you promised back on November 1, 2005. We will include any such explanation in an appropriate motion to the Court.

#FOLEY

Preston K. Ratliff II, Esq December 6, 2005 Page 2

Sincerely,

Steven A. Maddox

cc: Martin Endres William Cattie Herschel Sparks

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PRESTON K. RATLIFF || DIRECT DIAL (212) 218-2569 E-MAIL praint@fchs.com

December 7, 2005

VIA FACSIMILE

Steven A. Maddox, Esq. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007-5143

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Maddox:

This is in response to Andrx's December 6, 2005 letter regarding consolidation, Biovail's initial disclosures under Rule 26(a), and a protective order.

Regarding consolidation, as Andrx knows, the existing schedule in Biovail's view is ambitious. Whether Biovail can agree to consolidate the new lawsuit, directed to five additional tablet strengths, will depend on whether or not Andrx timely produces the documents and things Biovail is entitled to. While Biovail would like to consolidate on the existing schedule, it is not now in a position to make that commitment.

Regarding Biovail's initial disclosures under Rule 26(a), Biovail disagrees that Andrx has met its meet and confer obligations. Biovail's November 29, 2005 letter requested, among other things, that Andrx identify the authority it relies on for the proposition that Biovail should identify persons relevant only to secondary considerations of nonobviousness, when those persons are not relevant to any claim of Biovail, and are not relevant to any articulated defense of Andrx. Please provide a response to this point as well as to the other points raised in Biovail's November 29, 2005 letter.

Regarding the protective order, a draft is attached. Further, if a protective order has not been entered by December 30, 2005, Biovail agrees that its production by that date will be on a outside counsel eyes' only basis, provided that Andrx agrees to do the same with respect to its production by that date.

Steven A. Maddox, Esq. December 7, 2005 Page 2

Finally, Andrx did not send a copy of its December 6, 2005 letter to Biovail's local counsel, Jack Blumenfeld. As requested in Biovail's November 29, 2005 letter, please copy Mr. Blumenfeld on all correspondence.

Very truly yours,

Preston K. Ratliff II

cc: Jack B. Blumenfeld, Esq. William J. Cattie, III, Esq. Martin P. Endres, Esq. Herschel Sparks, Esq.

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PRESTON K. RATLIFF II DIRECT DIAL (212) 218-2569 E-MAIL pratif@fchs.com CALIFORNIA OFFICE

650 Town Center Drive, Suite 1600 Costa Mesa, California 92626-7130 (714) S40-8700 FACSIMILE (714) 540-9823

November 10, 2005

VIA FACSIMILE

Steven A. Maddox, Esq. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007-5143

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Maddox:

This concerns today's telephone scheduling conference with the Court.

During the conference, Andrx remarked that it was waiting for a response to its November 3, 2005 discovery proposal. As Andrx already knows, Biovail responded the next day, November 4, 2005, and offered a counterproposal to Andrx (see letter attached at Tab A). In this regard, please let Biovail know whether Andrx will agree to provide samples and the other information requested in Biovail's July 19, 2005 letter and in its first set of document requests by December 30, 2005. Also, please confirm that Andrx's production by that date will include its samples and documents for all proposed strengths of generic Cardizem LA, including those strengths that are the subjects of Civil Action No. 05-730.

Very truly yours,

Preston K. Ratliff II

Attachment

cc: William J. Cattie, III, Esq. Jack B. Blumenfeld, Esq.

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December 16, 2005

VIA FACSIMILE

WASHINGTON OFFICE

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(202) 530-1010

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Steven A. Maddox, Esq. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007-5143

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Maddox:

This concerns Andrx's responses to Biovail's first set of requests for documents and things, Andrx's letter of December 9, 2005, and Andrx's two letters of December 13, 2005 regarding Biovail's responses to Andrx's first set of requests for documents and things.

As an initial matter, Biovail is disappointed that Andrx requested a telephone conference with the Court to discuss alleged problems with Biovail's initial disclosures under Rule 26(a) and Biovail's responses to Andrx's first set of requests for documents and things. Andrx has not met its meet and confer obligations on either issue.

As to Biovail's initial disclosures, despite Biovail's November 29, 2005 and December 7, 2005 letters, Andrx still has not told Biovail why, among other things, it believes that Biovail should have identified persons relevant to only secondary considerations of nonobviousness, when those persons are not relevant to any of claim of Biovail, and are not relevant to any articulated defense of Andrx. As to Biovail's responses to Andrx's first set of requests for document and things, Andrx had not even given Biovail a reasonable opportunity to consider Andrx's 21 item December 9, 2005 complaint letter.

As to Andrx's responses to Biovail's first set of requests for documents and things, the majority of Andrx's responses are objections to producing materials that Biovail is plainly entitled to, or either are ambiguous responses that leave indeterminable what

Steven A. Maddox, Esq. December 16, 2005 Page 2

materials Andrx has agreed to produce. Yet, rather than broach each of these issues with Andrx now, Biovail believes that the prudent course is to await Andrx's production of documents due by December 30, 2005 to determine whether, in fact, Andrx seeks to withhold materials that Biovail is entitled to. Andrx's responses to Biovail's requests for samples, however, compel Biovail to seek clarification now.

Biovail Request Nos. 23 and 55 seek, among other things, samples of each strength of Andrx's proposed generic Cardizem LA products, and the materials that make up those products, including samples of Andrx's active pellets and extended-release pellets. Andrx stated in its December 6, 2005 letter that its production by December 30, 2005 will include samples for "all dosage strengths" covered by its ANDA. However, in its responses to Biovail's requests for documents and things (served the next day, on December 7, 2005), Andrx states that it has produced or will produce, if reasonably available, samples of its proposed products. As Andrx already knows, the samples that it previously provided to Biovail were damaged, and did not include samples of Andrx's active pellets. (See Biovail's October 7, 2005 letter). Moreover, Biovail fails to understand how Andrx's samples could not be "reasonably available." Please tell Biovail whether Andrx will produce, as requested, 120 tablets of each strength of Andrx proposed generic Cardizem LA products, as well as, 2 gram samples of the materials that make up those products, including but not limited to 2 gram samples of the active pellets and extended-release pellets.

As to Biovail's responses to Andrx's first set of requests for documents and things, Biovail addresses below each numbered paragraph of Andrx's December 9, 2005 letter.

- 1. In General Objection No. 15, Biovail objected to producing a duplicate set of the materials that Biovail provided to Andrx in the Tiazac® litigation. Despite Andrx's November 3, 2005 letter stating that it only needed "access" to the documents that Biovail provided in the Tiazac® litigation, Andrx now states that Biovail should produce a duplicate copy of the documents it provided to Andrx. Andrx's position is inconsistent with Andrx's General Objection No. 10, where Andrx objected to Biovail's requests to the extent that they called for the production of materials that Andrx provided to Biovail in the Tiazac® litigation. Now that Andrx requests that Biovail produce a duplicate set of Biovail's production in the Tiazac® litigation, please let Biovail know whether Andrx agrees to produce a duplicate set of the documents it produced in that litigation.
- 2. In General Objection No. 7, Biovail objected to producing documents to the extent that Andrx's requests seek documents beyond those relating to the "formulation" of Biovail's Cardizem LA products. In its December 9, 2005 letter, Andrx contends that Biovail's own requests go far beyond the "formulation" of Andrx's product, and therefore Biovail's General Objection No. 7 is allegedly frivolous or was made in bad faith. Documents regarding, for example, the research and development of Biovail's Cardizem LA products have no bearing on the only issue in this case, i.e., Andrx's infringement of the '791 patent. However, in the spirit of cooperation, Biovail will produce research and development documents, including laboratory notebooks. These documents,

Steven A. Maddox, Esq. December 16, 2005 Page 3

however, were not previously collected, and because of the scheduled end of the year shutdown of Biovail facilities, and the unavailability of Biovail personnel during the holidays, their production may not be completed by December 30, 2005. Biovail will endeavor to produce these documents as soon as practicable.

Document 37-2

- In General Objection No. 9, Biovail objected to producing documents relating to products offered for sale or sold outside of the United States. The basis for this objection is, of course, that such documents have no relevance to Andrx's infringement of the '791 patent. If Andrx has a reason why such documents are relevant to this case, please let Biovail know.
 - 4. See Biovail's response to numbered paragraph 1.
 - See Biovail's response to numbered paragraph 2. 5.
 - 6. See Biovail's response to numbered paragraph 2.
- 7. In response to Request Nos. 14-16 and 20-23, Biovail objected to producing documents regarding secondary considerations of nonobviousness. Biovail has repeatedly requested that Andrx explain why secondary considerations of nonobviousness are relevant where Andrx has not articulated any defense of invalidity. Please provide a response to the points raised in Biovail's November 29, 2005 and December 7, 2005 letters, and Biovail will reconsider Andrx's request.
- 8. In response to Request No. 19, Andrx contends that Biovail objected to producing Biovail's communications with the F.D.A. regarding Cardizem LA. This is also incorrect. Biovail will produce pertinent communications it had with the F.D.A. regarding its Cardizem LA products.
- 9. In response to Request No. 24, Andrx contends that Biovail objected to producing any documents that refer or relate to the '791 patent. This is incorrect. As drafted, Request No. 24 is vague, ambiguous, overly broad and unduly burdensome. If Andrx seeks something specific by this request, please let Biovail know.
- In response to Request No. 25, Biovail objected to producing 10. documents that are publicly available, such as the patents sought in Andrx's request. Please explain why Andrx believes that Biovail should produce copies of publicly available patents.
- In response to Request No. 28, Biovail objected because the request is vague, ambiguous, overly broad and unduly burdensome. Please tell Biovail exactly what Andrx seeks by this request, and Biovail will reconsider it.
- In response to Request No. 29, Biovail objected because the request is 12. overly broad and unduly burdensome as it called for all documents that refer or relate to

Steven A. Maddox, Esq. December 16, 2005 Page 4

Galephar, P.R. without limitation as to time or subject matter. Please tell Biovail exactly what Andrx seeks by this request, and Biovail will reconsider it.

- 13. In response to Request No. 30, Biovail objected because the request is vague, ambiguous, overly broad and unduly burdensome. Please tell Biovail exactly what Andrx seeks by this request, and Biovail will reconsider it.
- 14. In response to Request No. 31, Biovail objected because the request is vague, ambiguous, overly broad and unduly burdensome. Biovail further objected because the request is irrelevant to the only issue in this case, Andrx's infringement of the '791 patent. Please explain exactly why the access to Biovail facilities that Andrx seeks is relevant to this litigation.
 - 15. See Biovail's response to numbered paragraph 7.
- 16. In response to Request No. 38, Biovail objected to the request because it is vague, ambiguous, overly broad and unduly burdensome. Biovail further objected to the extent the request compels Biovail to search or analyze publicly available documents. Please tell Biovail exactly what Andrx seeks by this request, and Biovail will reconsider it.
 - 17. See Biovail's response to numbered paragraph 8.
- 18. In response to Request Nos. 50, Andrx contends that Biovail objected to producing documents referred to or relied on by Biovail in its pleadings. This is incorrect. Moreover, Request No. 50 does not call for documents "referred to or relied on by Biovail in its pleadings." If there is something specific that Biovail seeks by this request, please let Biovail know.
- 19. In response to Request Nos. 51 and 52, Biovail objected because the requests are vague, ambiguous, overly broad and unduly burdensome. Please tell Biovail exactly what Andrx seeks by these requests, and Biovail will reconsider it.
- 20. In response to Request No. 59, Biovail objected because the request is vague, ambiguous, overly broad and unduly burdensome. Biovail further objected because the request is irrelevant to the only issue in this case, Andrx's infringement of the '791 patent. Please tell Biovail exactly what Andrx seeks by this request, and Biovail will reconsider it.
- 21. In response to Request Nos. 60-62, Biovail objected because the requests are vague, ambiguous, overly broad and unduly burdensome. Biovail further objected because the requests are irrelevant to the only issue in this case, Andrx's infringement of the '791 patent. Please explain why the documents that Andrx seeks are relevant to this litigation.

Steven A. Maddox, Esq. December 16, 2005 Page 5

Very truly yours,

Preston K. Ratliff II

cc: Jack B. Blumenfeld, Esq. William J. Cattie, III, Esq. Martin P. Endres, Esq. Herschel Sparks, Esq.

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December 28, 2005

VIA FACSIMILE

Matthew C. Marlowe, Esq. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007-5143

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Marlowe:

This concerns Andrx's December 23, 2005 letter in response to Biovail's December 16, 2005 letter.

First, Biovail agrees that the parties should "annunciate" their positions when attempting to resolve disputes. In this regard, Biovail has repeatedly told Andrx that there is no reason to identify persons or produce documents that are only relevant to secondary considerations of nonobviousness where Andrx has failed to articulate any obviousness defense (boilerplate aside). Notwithstanding that, Biovail's responses to Andrx's interrogatories identify the names and addresses of persons sought by Andrx, such as the '791 patent inventors, and a Biovail employee knowledgeable regarding the sales of Cardizem® LA. On the other hand, Andrx has not identified any authority, or stated its reasons why it believes that Biovail should identify persons and produce documents that are relevant only to secondary considerations of nonobviousness. Please annunciate Andrx's position. Further, if Andrx fully articulates and supports a prima facie obviousness position in response to Biovail's interrogatories served on December 2, 2005, Biovail reserves the right to present its proofs of secondary considerations of nonobviousness.

Second, Biovail told Andrx in its November 29, 2005 letter that it would return all of the samples that Andrx provided on October 4, 2005 if Andrx agreed to provide new samples for all proposed strengths of its product by December 30, 2005. Andrx has not yet made that commitment. Moreover, Andrx stated in its December 23, 2005 letter that it

Page 42 of 55

Matthew C. Marlowe, Esq. December 28, 2005 Page 2

will only provide samples of finished product for its lower strength products, and "representative" samples of its active and extended-release beads. This is unacceptable. Biovail requested 120 tablets of each strength of Andrx's proposed generic Cardizem LA products, as well as, 2 gram samples of <u>all</u> materials that make up those products, including but not limited to 2 gram samples of the active and extended-release beads. *See* Biovail Request Nos. 23 and 55, as well as, Biovail's July 19, 2005, August 4, 2005, October 7, 2005, and November 10, 2005 letters. Please produce all requested samples by December 30, 2005.

Third, Biovail agrees to supplement the document production by Biovail that Andrx has retained from the Tiazac® litigation if Andrx agrees to supplement the document production by Andrx that Biovail has retained from that litigation. A list of the documents requested by Biovail is attached at Tab A.

Fourth, as to Andrx Request No. 50, Biovail has not refused to produce responsive documents. Request No. 50 is duplicative of other Andrx requests, and Biovail has agreed, for example, to produce pertinent portions of its NDA for Cardizem® LA. To the extent that Request No. 50 calls for other documents related to the pleadings, such documents are either protected by the attorney-client privilege and work product doctrines, or are in the possession of Andrx. As to Andrx Requests Nos. 51-52, Biovail does not see the relevance of "any and all" documents relating to patents or patent applications where Arthur Deboeck or Phillippe Baudier are named as inventors. As Andrx knows, Messieurs Deboeck and Phillipe are not employees of Biovail. Biovail's current understanding is that the requested documents are not in its possession, and it will confirm that understanding promptly after the New Year's holiday.

Finally, it is unclear from Andrx's responses to Biovail's first set of requests for documents and things what, if any, documents Andrx is withholding based on its General Objections. If Andrx is withholding documents based on its General Objections, please identify what documents it is withholding. Further, where Andrx has agreed to produce documents, in the majority of instances it stated that it will produce documents that "on their face" constitute, describe, reflect, relate, or refer to a particular subject. Please explain what is meant by this language, and identify what documents Andrx is withholding because they do not "on their face" constitute, describe, reflect, relate, or refer to the subject of Biovail's requests.

Very truly yours,

Preston K. Ratliff II

Matthew C. Marlowe, Esq. December 28, 2005 Page 3

cc: By Facsimile

Jack B. Blumenfeld, Esq. William J. Cattie, III, Esq. Martin P. Endres, Esq. Herschel Sparks, Esq.



FOLEY & LARDNER LLP ATTORNEYS AT LAW

WASHINGTON HARBOUR 3000 K STREET, N.W., SUITE 500 WASHINGTON, D.C. 20007-5143 202.672.5300 TEL 202.672.5399 FAX WWW.foley.com

December 29, 2005

WRITER'S DIRECT LINE 202.6725391 mmarlowe@foley.com EMAIL

CLIENT/MATTER NUMBER 054657-0103

Preston K. Ratliff II, Esq. Fitzpatrick, Cella, Harper & Scinto 30 Rockefeller Plaza New York, NY 10112-3801

Re:

Biovail v. Andrx Pharmaceuticals LLC et al., Civil Action No. 1:05-cv-586

Dear Mr. Ratliff:

I am writing in response to your letter of December 28th.

First, it is unfortunate that you waited until December 28th – just 2 days before the target production date of December 30th – to identify documents that you wished Andrx to re-produce from its prior production. We will look into whether Andrx still has the Bates numbered documents on your list, and arrange for re-production as soon as reasonably possible.

Second, there is nothing more to confer about with respect to Biovail's position that it need not produce documents relating to invalidity on the ground that Andrx's invalidity allegations are somehow insufficient. Biovail had a chance to challenge the sufficiency and/or clarity of Andrx's allegations at the time Andrx filed them. Biovail chose not to do so. The allegations of validity are in the case, and Biovail will be subject to sanctions for refusing to provide the requested discovery, which Biovail concedes to be relevant to the issue of invalidity. This is just another instance of Biovail's litigation misconduct and violation of its duty to expedite this case. We will take this to Judge Jordan.

Third, Biovail's failure to return the allegedly "damaged" and "unusable" samples makes it difficult to conclude that you were being altogether truthful in asserting the "damage" as the reason for needing additional samples. We stand by our offer to replace the "damaged" samples once you return them to us. The rest of your complaints about samples are simply ridiculous. Andra cannot provide samples of materials that it does not have. Just because you want something does not mean that it exists.

Fourth, we find equally fatuous your complaint about the term "on its face" in connection with determining whether a document is responsive. It means that we determine responsiveness

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Preston K. Ratliff II, Esq December 29, 2005 Page 2

by looking at the documents themselves that we pull from the files that are reasonably likely to contain at least some relevant documents.

Very Truly Yours,

Matthew C. Marlowe

Jack Blumenfeld cc: William Cattie Martin Endres

A Back



Andrx Corporation Press Release



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Press Releases

Board of Directors

(Nasdaq:ADRX) (Andrx or the Company) today announced that the FDA's Florida (ANDAs) on hold. This action resulted from the FDA inspection of the Company's FORT LAUDERDALE, Fla.~-(BUSINESS WIRE)--Sept. 6, 2005--Andrx Corporation District office has placed Andrx in OAI (Official Action Indicated) status, thereby the Company's response or corrective action plan. The May 2005 Form 483 and which included a proposed corrective action plan. FDA has not commented on the Company's response were disclosed in the Company's Form 10 Q for the manufacturing facilities that ended in May 2005 and the FDA's issuance of placing FDA approval of the Company's abbreviated new drug applications inspection. Andrx provided FDA with a detailed response to that Form 483, Form 483 -- List of Inspectional Observations at the conclusion of that period ended June 30, 2005.

Andrx is working to resolve the cGMP issues at its facility as quickly as possible. The timing of that resolution is uncertain, and is not solely in our control

Information Request

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IR Contact

FDA also has the authority to revoke previously granted drug approvals. Should FDA obtain these types of sanctions, which are noted in the Company's Annual FDA could seek various sanctlons against Andrx for violations of current Good Manufacturing Practices (cGMP), or other applicable statutes and regulations. suspension of the FDA's review of product applications, enforcement actions, injunctions and civil or criminal prosecution. Under some circumstances, the Reports, it could have a material adverse affect on the Company's results of seizures, fines, total or partial suspension of production and/or distribution, The range of possible sanctions includes, among others, product recalls or operations and financial condition.

About Andrx Corporation

We are a pharmaceutical company that:

http://phx.corporate-ir.net/phoenix.zhtml?c=65308&p=irol-newsArticle&ID=752885&highlight=

Andrx Corporation Press Release

- develops, manufactures and commercializes generic versions of controlled-release, niche and immediate-release pharmaceutical products, including oral contraceptives;
- distributes pharmaceuticals, primarily generics, which have been commercialized by others, as well as our own, primarily to independent pharmacies, pharmacy chains, pharmacy buying groups and physicians' offices; and
- develops and manufactures pharmaceutical products for other pharmaceutical companies, including combination products and controlled-release formulations utilizing our patented technologies and formulation capabilities.

release are made pursuant to the safe harbor provisions of the Private Securities uncertainties, including but not limited to, what sanctions, if any, FDA may seek, following its decision to place Andrx in OAI status, and when the "hold" on the or loss of customers; our relationship with our suppliers; the success of our joint number of products; licensing revenues; the timing and scope of patents issued statements of historical fact may be deemed to be forward-looking statements orward-looking statements (statements which are not historical facts) in this Company's ANDA approvals will be lifted; our dependence on a relatively small marketing exclusivity period and, if so, the precise dates thereof; government manufacturing requirements of the First Horizon agreement; the consolidation suppliers; the impact of sales returns and allowances; product liability claims; comparable terminology are intended to identify forward-looking statements. Investors are cautioned that all forward-looking statements involve risk and Without limiting the generality of the foregoing, words such as "may," "will, nability to obtain sufficient supplies and/or active pharmaceuticals from key litigation Reform Act of 1995. For this purpose, any statements contained associated with, acquisitions of technologies, products and businesses; our regulation generally; competition; manufacturing capacities, safety issues, herein or which are otherwise made by or on behalf of Andrx that are not to our competitors; the timing and outcome of patent, antitrust and other development and marketing expenses that may not result in commercially commercialize new products; the loss of revenues from existing products; successful products; our inability to obtain, or the high cost of obtaining, "to," "plan," "expect," "believe," "anticipate," "intend," "could," "would, "estimate," or "continue" or the negative or other variations thereof or litigation and future product launches; whether we will be awarded any icenses for third party technologies; our ability to meet the supply and ventures; difficultles in integrating, and potentially significant charges output and quality processes; our ability to develop and successfully

Andrx Corporation Press Release

rising costs and limited availability of product liability and other insurance; recent management changes and the potential loss of senior management and other key personnel; failure to comply with environmental laws; the absence of certainty regarding the receipt of required regulatory approvals or the timing or terms of such approvals; and our ability to commercialize all of our pre-launch inventory. Actual results may differ materially from those projected in a forward-looking statement. We are also subject to other risks detailed herein or detailed from time to time in our Annual Report on Form 10-K for the year ended December 31, 2004 or in our other SEC fillings. Subsequent written and oral forward-looking statements attributable to us or to persons acting on our behalf are expressly qualified in their entirety by the cautionary statements set forth in our Annual Report on Form 10-K for the year ended December 31, 2004 and in our other SEC fillings.

This release and additional information about Andrx Corporation is also available on the Internet at: http://www.andrx.com.

CONTACT: Andrx Corporation Angelo C. Malahias, 954-382-7600

SOURCE: Andrx Corporation

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: Statements in this press release regarding Andrx's business which are not historical facts are "forward-looking statements" that involve risks and uncertainties. For a discussion of such risks and uncertainties, which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report or Form 10-K for the most recently ended fiscal vear.

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January 6, 2006

VIA FACSIMILE

FACSIMILE (202) 530-1055

Matthew C. Marlowe, Esq. Foley & Lardner LLP 3000 K Street, N.W. Suite 500 Washington, DC 20007-5143

Re:

Biovail v. Andrx Pharmaceuticals LLC et al.,

Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Marlowe:

This concerns the remarks in Andrx's December 29, 2005 letter regarding Biovail's requests for samples.

Regarding the damaged samples that Andrx sent Biovail on October 4, 2005, Biovail accepts Andrx's offer to replace those samples. Biovail will return the damaged samples to Andrx's New York counsel, the Hedman & Costigan firm, under separate cover.

Regarding Biovail's requests for samples of each individual ingredient used in the manufacture of the samples of finished tablets that Andrx has produced, please explain what is meant by Andrx's statement that it "cannot provide samples of materials that it does not have." Certainly, if Andrx is suggesting that it does not have one or more of the requested samples, it should have told Biovail that many months ago, prior to agreeing to produce these samples. In addition, if Andrx does not have one or more of the requested samples, please provide documentation reflecting how those materials were consumed. Further, to avoid any misunderstanding as to which samples Andrx has failed to produce, a list of the remaining samples requested is attached at Tab A. Please promptly provide the samples requested.

Finally, in anticipation of receiving the remainder of the samples requested by Biovail, please confirm that the confidentiality undertakings executed by Professors Langer and Davies on August 4, 2005 and August 5, 2005, respectively, apply to all documents, samples, and other materials that Andrx produces in the litigations. Biovail will, of course,

Matthew C. Marlowe, Esq. January 6, 2006 Page 2

provide additional undertakings upon the entry of a protective order by the Court. If Andrx does not immediately agree to these requests, please be aware that Biovail will seek appropriate remedies from the Court, including an extension of the schedule to account for any delay in Biovail's experts being able to examine <u>all</u> of the requested samples.

Very truly yours,

Preston K Ratliff II

cc: Via Facsimile

Jack B. Blumenfeld, Esq. William J. Cattie, III, Esq. Martin P. Endres, Esq. Herschel Sparks, Esq.

Requested Samples

Page 55 of 55

- 1. 2 grams of the batch of active pellets used in the manufacture of Andrx's 420 mg tablets (Lot REDACTED);
- 2. 2 grams of the batch of Eudragit NE 30D used in the manufacture of Andrx's 420 mg tablets (Lot **REDACTED**);
- 3. Replacement samples of the Andrx samples designated ANDRX 00020 and ANDRX 00021; and
- 2 grams of the batch of each individual ingredient, including the active pellets and extended release pellets, used in the manufacture of Andrx's 120, 180, 240, 300, and 360 mg tablets (Lots REDACTED, REDACTED, REDACTED, and REDACTED).